In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: June 2, 2022

DEBRA ALLEN,	*	PUBLISHED
Petitioner,	*	No. 15-1278V
v.	*	Special Master Gowen
SECRETARY OF HEALTH AND HUMAN SERVICES	*	Ruling on Entitlement; Shoulder Injury; Adhesive Capsulitis; Causation in Fact; Intradermal Influenza ("flu") vaccine.
Respondent.	*	

Howard S. Gold, Howard S. Gold, Sudbury, MA, for petitioner.
Althea W. Davis, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

On October 28, 2015, Debra Allen ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program.[2] Petitioner alleges that as a result of receiving an intradermal influenza ("flu") vaccine on October 1, 2013, in her left arm she suffered shoulder inflammation, adhesive capsulitis, and a shoulder injury related to vaccine administration ("SIRVA") that was caused in fact by the flu vaccination. Petition (ECF No. 1); Amended Petition (ECF No. 64).

The parties agreed to submit this case for a ruling on the record. After a review of the record including expert reports, medical records, medical literature, affidavits, and briefing by

[1] Pursuant to the E-Government Act of 2002, see 44 U.S.C. § 3501 note (2012), **because this opinion contains a reasoned explanation for the action in this case, I intend to post it on the website of the United States Court of Federal Claims.** The Court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. Before the opinion is posted on the Court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). An objecting party must provide the Court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the Court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

the parties, and for the reasons set forth below, I hereby find that petitioner has carried her burden by preponderant evidence that she is entitled to compensation.

I. Procedural History

Petitioner filed her original petition on October 28, 2015, alleging she sustained a left shoulder injury and Fibromyalgia/Polyarthropathy after receiving an intradermal flu vaccine on October 1, 2013. Petition (ECF No. 1). The case was initially referred to the Special Processing Unit ("SPU"). *See* SPU Initial Order (ECF No. 5). On March 4, 2016, respondent submitted a status report indicating that he was not amendable to exploring settlement. Respondent ("Resp") Status Report ("Rept.") (ECF No. 13). On April 18, 2016, respondent filed the Rule 4(c) Report, stating that compensation is not appropriate because petitioner could not establish that she suffered a table SIRVA, and with respect to the Fibromyalgia/Polyarthropathy injury petitioner failed to present a prima facie case of causation. Resp. Rept. at 5 (ECF No. 14). Specifically, respondent stated that the petitioner's alleged symptoms are not consistent with a SIRVA injury, because the onset did not occur within an appropriate time frame, and petitioner's alleged symptoms spread to other areas of her body. Resp. Rept. at 5.

On May 12, 2016, Special Master Dorsey issued a scheduling order indicating that the parties agreed to consider a reasonable settlement. (ECF No. 15). On August 5, 2016, petitioner submitted a status report indicating that a settlement demand was forwarded to respondent. (ECF No. 22). Settlement negotiations between the parties stalled and on September 16, 2016, the case was transferred to my docket. Notice of Reassignment (ECF No. 27).

I held a status conference on September 28, 2016, where petitioner confirmed there are two separate vaccine injury claims in this case, and respondent confirmed her position that an intradermal injection was incapable of causing a mechanical SIRVA as alleged. (ECF No. 28). Additionally, there was some question about whether the vaccine was administered intradermally despite the indication on the vaccine record and petitioner also alleged an autoimmune condition and therefore I explained that petitioner would need to get expert reports to address whether the vaccine administered by an intradermal injection system was capable of causing shoulder pain as experienced by the petitioner. *Id*.

On February 20, 2017, petitioner filed an expert report from Dr. Eric Gershwin.[3] Petitioner's ("Pet.") Exhibit ("Ex.") 8 (ECF No. 33). On May 30, 2017, respondent filed a

[3] Dr. Gershwin graduated with a Bachelor of Science degree in mathematics from Syracuse University in 1966 and a medical degree from Stanford University in 1971. Pet. Ex. 14 at 1. He completed an internship and residency at Tufts-New England Medical Center, then served as a clinical associate in immunology at the National Institutes of Health. *Id.* at 2. In 1975, Dr. Gershwin joined the University of California Davis (UC Davis) School of Medicine to start its immunology program. *Id.* at 1. He is currently the Jack and Donald Chia Professor and a Distinguished Professor of Medicine in the divisions of Rheumatology/ Allergy and Clinical Immunology at UC Davis. *Id*. Dr. Gershwin is licensed to practice medicine in the state of California. He is board-certified in internal medicine, rheumatology, allergy, and clinical immunology. *Id.* at 2. Dr. Gershwin highlighted that he has been awarded an honorary doctorate degree by the University of Athens, home of the Hippocratic Oath, for lifetime achievement in immunology. *Id*.

responsive expert report from Dr. Harry Schroeder.[4] Resp. Ex. A (ECF No. 37). A Rule 5 Status conference was held on June 6, 2017, during which I explained that the main challenge for petitioner is to establish a causal relationship between the flu vaccine and her secondary symptoms. Scheduling Order at 1 (ECF No. 38). I gave the parties the opportunity to engage in settlement discussions once again. *Id*. at 2.

On July 11, 2017, petitioner filed a status report stating that she had forwarded a revised demand to respondent. Pet. Status Rept. (ECF No. 39). On August 10, 2017, respondent filed a status report indicating that the parties were unable to reach an informal resolution. Resp. Status Rept. (ECF No. 40). A status conference was held on September 14, 2017, where the respondent stated that the intradermal method of vaccination administration could not have caused petitioner's injuries, and petitioner agreed that she received an intradermal vaccine, but clarified that she is not alleging a mechanical injury, but an inflammatory response. Scheduling Order at 1 (ECF No. 41). I also ordered the parties to file a status report indicating their mutual availability for a hearing, and for the parties to consider an alternative means of resolution. *Id*. at 2.

On October 12, 2017, a hearing order was issued setting a hearing for December 3-4, 2019. Hearing Order (ECF No. 43). A status conference was held on May 9, 2019, and on May 14, 2019, I set the pre-hearing order for the parties to submit pre-hearing briefs. (ECF No. 51). On July 5, 2019, petitioner filed a supplemental expert report from Dr. Eric Gershwin. Pet. Ex. 9 (ECF No. 54).

On September 19, 2019, I issued a scheduling order cancelling the December 3-4, 2019, entitlement hearing. (ECF No. 59). On September 20, 2019, respondent filed an expert report from Dr. Harry W. Schroeder. Resp. Ex. C (ECF No. 60). I held a status conference on October 21, 2019, during which I explained that petitioner's injury is consistent with a SIRVA claim and recommended that petitioner refine her claim. Scheduling Order (ECF No. 63). I explained that the intradermal method of administration was not made available for the 2018 – 2019 flu seasons, or the 2019 – 2020 flu seasons, and the manufacturer has ceased production of the intradermal injector for the flu vaccine. *Id*. Petitioner filed an amended petition on November 11, 2019, focusing her claim and alleging that petitioner suffered a SIRVA which was "caused-in-fact" by her intradermal flu vaccination. Amended Petition (ECF No. 64).

A status conference was held on June 15, 2020, and I directed respondent to file a status report on the prospect of informal resolution. Scheduling Order (ECF No. 68). On July 8, 2020, respondent filed a status report indicating that he was not amenable to informal resolution and

[4] Dr. Harry Schroeder obtained a bachelor's degree in chemistry in 1974 from Texas A & M University, a M.D. from Baylor College of Medicine in 1981 and a Ph.D. in cell biology in 1979 from Baylor College of Medicine. Resp. Ex. B. He completed an internship at the University of Kentucky in Lexington, Kentucky. *Id*. at 2. Dr. Schroeder then went to the University of Washington where he obtained training in medical genetics. *Id.* He is board certified in internal medical and clinical genetics. *Id.* at 4. From 1986-1988 he pursued training in immunology, molecular immunology at the Howard Hughes Institute in Seattle, Washington. *Id*. at 2. Dr. Schroeder began a teaching career at the University of Alabama at Birmingham in 1988. *Id*. Dr. Schroeder spent a sabbatical year at the University of Cologne in Cologne Germany at the Institute of Genetics under the mentorship of Klaus Rajewsky. *Id*. at 3. He is currently a Director of the University of Alabama at Birmingham ("UAB") in Immunology and Director of the T32 Training Program in Immunologic Diseases and Basic Immunology at UAB. *Id*. at 3. Dr. Schroeder also serves as an associate editor for the American Journal of Clinical and Experimental Immunology, and the Journal of immunology & Clinical Research, among others. *Id*. at 7.

wanted to move forward with the entitlement hearing set for December 3-4, 2020. (ECF No. 69). I issued a scheduling order on July 9, 2020, and ordered petitioner to file an expert report addressing causation-in-fact between the intradermal vaccine and the injuries in question. Scheduling Order (ECF No. 70).

On August 18, 2020, petitioner filed an expert report from Dr. Steven Graboff, an orthopedic surgeon.[5] Pet. Ex. 11 (ECF No. 71). Respondent filed a responsive expert report from Dr. Paul J. Cagle, also an orthopedist.[6] Resp. Ex. D (ECF No. 72). I held a status conference on October 7, 2020, and directed the parties to propose further proceedings. Scheduling Order (ECF No. 77). The parties filed a joint status report on November 9, 2020, and requested a ruling on the record and cancelled the December 3-4, 2020, entitlement hearing. Joint Status Rept. (ECF No. 78). On November 23, 2020, respondent filed a supplemental expert report from Dr. Cagle. Resp. Ex. F (ECF No. 79). On December 17, 2020, petitioner filed a supplemental expert report from Dr. Graboff. Pet. Ex. 12 (ECF No. 80).

On January 31, 2021, petitioner filed a motion for a ruling on the record. Pet. Motion ("Pet. Mot.") (ECF No. 82). Respondent filed a response to petitioner's motion on March 3, 2021. Resp. Response (ECF No. 83). Petitioner filed a reply on March 5, 2021. Pet. Reply (ECF No. 85). I held a status conference regarding the six cases involving intradermal flu vaccines and Mr. Ryan Pyles, speaking on behalf of respondent, raised an objection and expressed the desire to move forward with each case individually. Order (ECF No. 86).

This matter is now ripe for adjudication.

II. Petitioner's Medical History

a. Medical Records

The petitioner was born on December 5, 1954, and before the vaccination in question she had no current illness, fever, or injuries in her arms or shoulders. Pet. Ex. 2 at 1. On October 1, 2013, petitioner received an intradermal flu shot in her left arm at her place of employment. Pet. Ex. 3 at 1. On October 21, 2013, petitioner filed a Work-Related Incident Report and noted

[5] Dr. Steven R. Graboff is an orthopaedic surgeon who retired from clinical practice on January 1, 2018. Pet. Ex. 11 at 1. He obtained a bachelor's degree from the University of California, Los Angeles in 1974, and an M.D. from the University of California Irvine School of Medicine in 1980. *Id*. He completed an internship in general surgery from the University of California Irvine Medical Center in 1981 and completed a residency in Orthopaedic Surgery from the UCLA Medical Center and Affiliated Hospitals from 1981-1985. *Id*. He was a member of various professional organizations and taught in a variety of settings on orthopedics. *Id*. 1-2.

[6] Dr. Paul J. Cagle is an orthopaedic surgeon who serves as an Assistant Professor and Associate Program Director in the Department of Orthopaedic Surgery at the Icahn School of Medicine at Mount Sinai. Resp. Ex. E at 1. Dr. Cagle received his medical degree from the Loyola University Chicago Stritch School of Medicine. *Id*. He did a residency in orthopaedic surgery at the University of Minnesota Academic Health Center and Medical School from 2008-2013. *Id.* He board certified in orthopaedic surgery. *Id.* Prior to working at Mount Sinai, Dr. Cagle was an assistant professor and interim chair of the Department of Orthopaedic Surgery at Southern Illinois University School of Medicine. *Id.* He has published numerous articles in peer reviewed journals. *Id*. at 3-14.

"severe swelling, hard lump + redness Oct. 8th. In Bermuda so did not see primary care physician until I got home on Oct. 21, 2013."[7] Pet. Ex. 4 at 1.

On October 24, 2013, petitioner visited her primary care physician ("PCP"), Dr. Bushra Khan, and was seen by Victoria H. Gantz a nurse practitioner, with complaints of "continued pain the posterior left shoulder with decreased range of motion," following a flu vaccine approximately 2.5-3 weeks ago. Pet. Ex. 5 at 63. The "History of Present Illness" noted there was no redness or tenderness on or near her left deltoid area, but that she did have a "moderate amount of decreased range of motion of the shoulder in all directions secondary to pain in the anterior posterior rotator cuff." *Id*. at 65. Petitioner was assessed as having a local reaction to the flu vaccine. *Id*.

On October 29, 2013, petitioner visited Dr. Robert McLaughlin, an orthopedist, for left shoulder pain. Pet. Ex. 6 at 1. Under "History of Present Illness," Dr. McLaughlin noted that petitioner reported "receiving a flu shot to the left arm 3 days after she began to experience redness, swelling, pain, and stiffness to the left shoulder. No injury occurred. No previous history of left shoulder pain or injury." *Id.* Petitioner reported that she has "constant soreness with intermittent sharp pain to the superolateral aspect of the left shoulder as well as to the upper lateral arm." *Id.* Dr. McLaughlin noted that petitioner's pain was "exacerbated by internal rotation, pulling motions, and motions away from the body." *Id.* It was also noted that petitioner had stiffness of the shoulder and the pain was waking her up at night. *Id.* During the physical exam of her left shoulder, petitioner demonstrated positive signs of impingement with positive Hawkins and Neer's tests. *Id*. Dr. McLaughlin's impression was, "I believe her shoulder pain is not directly related to her flu shot but she may have some discomfort and guarding of her shoulders which may have caused the beginning of some inflammation of her rotator cuff." *Id.* at 2. Dr. McLaughlin wrote, "..given the level of inflammation, I thought she would benefit from an injection of cortisone." *Id.* He diagnosed her with "rotator cuff syndrome of shoulder." *Id.*

Petitioner returned to her PCP, Dr. Khan on November 11, 2013, with complaints of pain in her left shoulder. Pet. Ex. 5 at 66. Dr. Khan noted that petitioner wanted an MRI, and it was ordered for November 17, 2013. *Id*. Under "Assessment," Dr. Khan noted that petitioner should attend a "trial of physical therapy to assess for [range of motion]." *Id*. at 69. On November 17, 2013, petitioner underwent an MRI and it revealed, "a small amount of abnormal fluid within the subdeltoid bursa," and "moderate distal supraspinatus tendinopathy associated with a moderate partial-thickness deep surface tear distally." Pet. Ex. 7 at 12. The radiology report also noted that, "a tiny pinpoint full-thickness perforation of the distal supraspinatus tendon is suspected given the small amount of fluid in the overlying subdeltoid bursa." *Id.* The MRI report also noted that she had mild to moderate distal infraspinous tendinopathy. *Id.*

Petitioner returned to Dr. McLaughlin on November 19, 2013, for an MRI follow up and reported that the cortisone shot from October 29, 2013, did not provide any relief. Pet. Ex. 6 at 3. Petitioner also reported that sleeping at night remains difficult and her PCP had prescribed Tylenol with Codeine, as well as physical therapy. *Id.* A physical examination of her left shoulder revealed that her passive abduction was 130 degrees, and her external rotation was 20 degrees. *Id.* Further, petitioner had mild impingement signs. *Id.* Dr. McLaughlin noted that

[7] The reference to Bermuda appears to be in error as all other references indicate that petitioner was in Aruba.

petitioner "has pain in extreme ranges of motion." *Id.* Dr. McLaughlin noted that petitioner had "some rotator cuff tendinopathy but without any obvious tear." *Id*. at 4. Under "Impression," Dr. McLaughlin noted that petitioner appears to be "beginning to develop a picture of early frozen shoulder…she also has some rotator cuff tendinopathy but without any obvious tear." *Id*. at 3-4. He recommended that petitioner continue with her normal daily activities and follow-up in one month. *Id.*

On December 1, 2013, petitioner presented to the emergency department complaining of left shoulder pain. Pet. Ex. 7 at 5. She reported that her pain had been present for two months and it started after receiving a flu vaccine in her left deltoid. *Id*. Petitioner also reported that she had been prescribed anti-inflammatory medication, but the pain continued. *Id.* Petitioner's exam of her left shoulder showed decreased range of motion secondary to discomfort. *Id.* at 6. Physician Assistant, David Alden St. Pierre, reviewed petitioner's MRI from November 17, 2013, and wrote, "it indicated that at least moderate distal supraspinatus tendinopathy associated with moderate partial-thickness deep surface tear distally…there is a tiny pinpoint full-thickness perforation of the distal supraspinatus tendon," and he noted a "small amount of fluid [in] the overlying subdeltoid bursa." *Id.* at 6.

An ultrasound was completed, which showed petitioner had a "calcific tendinopathy of the infraspinatus and supraspinatus" and "moderate to severe tendinopathy of the long head of the biceps tendon, but no definite joint effusion was identified." Pet. Ex. 7 at 9; Pet. Ex. 5 at 80. She was discharged with corticosteroids for pain relief, and recommended a follow up with Dr. McLaughlin, an orthopedist. *Id*. at 6.

During a follow-up appointment with Dr. McLaughlin on December 3, 2013, he noted that petitioner might have an inflamed bursa and recommended taking a two-week break from physical therapy. Pet. Ex. 6 at 5. Petitioner explained that she was experiencing "severe left shoulder pain for the last week," and that she went to the emergency department where an ultrasound of the left upper extremity was performed. *Id.* Petitioner also described a "constant throb to the anterior and suprolateral aspect of the left shoulder." *Id.* Dr. McLaughlin performed another exam of petitioner's left shoulder, which he noted she still have positive signs of impingement and pain at the end of range of motion in her left shoulder. *Id.* He stated that petitioner's MRI did not show obvious full-thickness rotator cuff tear and that he does "believe that [petitioner] is suffering from what appears to be early and intense frozen shoulder of her left shoulder." *Id.* at 5.

On December 6, 2013, petitioner saw Dr. Paul Smiley, an orthopedist, and noted that her x-rays were normal and that it was "likely the patient has significant inflammatory response to her flu shot." Pet. Ex. 5 at 86. Dr. Smiley injected petitioner's left shoulder with another cortisone injection. *Id*. Her history also noted a "history of a left shoulder arthroscopy in 1989." *Id*. at 85. Petitioner was diagnosed with left shoulder tendinopathy/tendinitis. *Id.* at 83.

Petitioner returned to Dr. Smiley on December 13, 2013. Pet. Ex. 7 at 78. He noted that petitioner reported some improvement with the cortisone injection, but she reported her pain returning. *Id.* He stated that petitioner's range of motion was "fairly good." He recommended that petitioner attempt to resume physical therapy, and if her pain gets worse again, she should

consider an aspiration arthrogram. *Id.* at 78. He also recommended petitioner see a rheumatologist. *Id.*

On December 16, 2013, petitioner saw Dr. Katz, a rheumatologist. Pet. Ex. 5 at 74. Dr. Katz explained that her white count was normal but that she had high inflammation markers. *Id*. at 77. Dr. Katz also observed that petitioner's range of motion on abduction of her left shoulder was consistent with adhesive capsulitis. *Id.* at 76. Petitioner was diagnosed with tendonitis of the left shoulder and arthralgias in multiple sites. *Id*. Dr. Katz stated that she did not believe petitioner's issues were related to an autoimmune connective tissue disorder or vasculopathy. *Id.*

On December 23, 2013, petitioner had an appointment with Nurse Practitioner Linda Sickorez. Pet. Ex. 5 at 72. Petitioner reported that the cortisone shot she received on December 6, 2013, was helpful for a limited period of time, but her pain had begun to return. *Id.* Petitioner described the pain as "excruciating." *Id.* The physical exam noted that petitioner had "fairly good range of motion in forward elevation, abduction, and internal rotation, but were all painful." *Id.* at 73. Additionally, petitioner demonstrated "mildly positive impingement." *Id.* Nurse Practitioner Sickorez recommended that petitioner undergo a "glenohumeral joint aspiration." *Id.*

On January 7, 2014, petitioner underwent a left shoulder arthroscopy, arthroscopic acromioplasty, manipulation under anesthesia, and rotator cuff repair. Pet. Ex. 5 at 102. Her preoperative diagnosis was of left shoulder impingement and her post-operative diagnosis of left shoulder impingement with rotator cuff tear. *Id*. Under "Description of Procedure" it was noted that petitioner underwent a left shoulder manipulation where, "20 degrees of abduction was obtained with audible lysis of adhesions," and there was a small full-thickness tear of the rotator cuff supraspinatus just posterior to the biceps tendon which was repaired. *Id.* Petitioner had a follow-up appointment on January 10, 2014, and it was noted that the surgery went well and that she should stay in her shoulder sling as much as possible. *Id*. at 98.

Petitioner returned to Dr. Katz on January 21, 2014, complaining of left shoulder pain. Pet. Ex. 5 at 91. It was also noted that petitioner was on a low dose of prednisone and that petitioner thought it was helping her shoulder. *Id*. Dr. Katz did not believe that petitioner was suffering from polymyalgia rheumatica or an underlying arthropathy, she instead thought it was likely generalized degenerative arthritis. *Id*. at 94. Petitioner returned to Dr. Katz on February 18, 2014, with discomfort and weakness in her arms and legs. *Id*. at 110. Dr. Katz ordered an EMG nerve conduction study of both upper and lower extremities and continued petitioner on the regimen of prednisone. *Id*. at 113-14. The EMG took place on March 13, 2014, and the results were normal. *Id*. at 10.

On March 26, 2014, petitioner returned to Dr. Katz after eight days of steroid treatment with only marginal improvement. Pet. Ex. 5 at 125. It is noted that petitioner found it hard to "extend her arms because of the stiffness and discomfort," and "she still believes that the left deltoid flu vaccination she received on October 1, 2013, caused the initiation of all of [her] symptoms." *Id*. Petitioner was evaluated by Dr. Kowal on March 27, 2014, a pain management specialist. *Id*. at 124. Dr. Kowal mentioned "her systemic inflammatory syndrome," and petitioner received an epidural injection in her lumbar spine. *Id*.

Petitioner returned to Dr. Smiley for a four-month follow up post-surgery on May 12, 2014. Pet. Ex. 5 at 148. He noted that, "she is still having some diffuse muscle aches, likely from the flu shot…but as far as her shoulder is concerned, her range of motion is good. She has negative impingement sign." *Id*. at 148. On June 24, 2014, petitioner returned to Dr. Katz when it was noted that petitioner "may have developed a myofascial pain syndrome secondary to her generalized osteoarthritis." *Id*. at 163.

On July 10, 2014, petitioner returned to Dr. Kowal who diagnosed her with a "syndrome of central pain amplification fibromyalgia." Pet. Ex. 5 at 193. Petitioner was given a prescription for Savella, a norepinephrine re-uptake inhibitor to help with her fatigue analgesia. *Id*. On July 17, 2014, Petitioner was evaluated by Dr. Moheban, a neurologist, who noted that she did not believe petitioner's symptoms were neurological in nature. *Id*. at 180-82. On July 24, 2014, petitioner was evaluated by Dr. Suchindran, an infectious disease specialist. *Id*. at 169. Dr. Suchindran noted that "perhaps her influenza vaccination triggered something, but I do not believe that there is an active viral process related to the vaccination ongoing." *Id*. at 173.

On August 19, 2014, petitioner was evaluated by Dr. Russell, a neurologist, who assessed petitioner with arthralgias in multiple sites, including the left shoulder, suggestive of an inflammatory disorder without identifiable neuromuscular disease. Pet. Ex. 5 at 210-11. On August 25, 2014, petitioner returned to Dr. Katz, and discontinued the use of steroids because she could not justify continuing the treatment. *Id*. at 199. Petitioner returned to Dr. Katz on October 1, 2014, with complaints of soreness in bilateral arms, fingers, wrists, knees, and feet. *Id*. at 228. On February 27, 2015, petitioner returned to Dr. Katz with "pain in her left neck radiating to her left shoulder." *Id*. at 234. Petitioner continued to attribute "all her body pain to the reaction to a flu vaccine last year." *Id*.

On May 21, 2015, petitioner presented to Dr. Robert Duncan "for evaluation of adverse reaction to flu shot given into her left shoulder." Pet. Ex. 5 at 286. Petitioner reported that she had a flu shot on October 1, 2013, and had immediate pain going down her left arm into her 2nd and 3rd fingers. *Id.* It was noted that petitioner stated the injection was given high on her shoulder near the joint "by an inexperienced nurse." *Id.* Petitioner also reported that she had difficulty moving her shoulder and that it was swollen. *Id.* Dr. Duncan recounted much of her history, including her MRI and left shoulder surgery. *Id.* It was noted that "the left shoulder is now benign, with most of her complaints elsewhere." *Id*. He also observed that her CRP level had returned to the 2-10 range. *Id.* at 287. After a physical assessment, Dr. Duncan wrote,

> This is a 60-year-old woman with what appears to have been a left shoulder injury following vaccination. This is apparently injected too high in the arm, apparently missing the deltoid muscle, and entering the joint and/or bursa of the left shoulder. With injection of flu antigen into the joint space and bursa this can produce bursitis and inflammatory arthritis. Although this is a remote event, it appears that she had immediate reaction following the vaccine and documented this, including an incident report. She had several months of symptoms, ultimately requiring arthroscopic evaluation with good results for the left shoulder which has essentially resolved.

Id. at 291.

On July 2, 2015, petitioner returned to Dr. Katz with complaints of muscle soreness and "if someone barely puts pressure on her forearm, she has discomfort." *Id*. at 312. On July 9, 2015, Dr. Kowal noted that petitioner has discontinued oral steroids. *Id*. at 325.

b. Petitioner's Affidavit

On October 21, 2015, petitioner executed a detailed affidavit. Pet. Affidavit ("Aff.") (ECF No. 9). Petitioner stated that on October 1, 2013, she received the influenza vaccination at the Beverly Hospital, the place of her employment. Pet. Aff. at ¶ 3. At the time of the vaccination petitioner was employed as a part-time laboratory technician. *Id*. at ¶ 20. Petitioner stated that prior to the vaccination she was in her usual health and had no current illness, fever, or injuries in her arms or shoulders. *Id*. at ¶ 5. She explained that when she received the vaccination she had an electric sensation in her arm, and a pain that she had never experienced during any other vaccination. *Id*. at ¶ 4. On October 3, 2013, petitioner traveled to Aruba for a previously scheduled vacation and noted that her "arm was aching and had that 'heavy feeling.'" *Id*. at ¶ 6.

On October 8, 2013, a week following the vaccination, petitioner stated she "developed a red area where the flu shot was administered," with pain in her shoulder and limited range of motion. *Id*. at ¶ 7. She explained that over the next several days the "local redness and swelling gradually resolved but the shoulder pain and limited mobility continued to get worse." *Id*. at ¶ 8. Due to her travel to Aruba, petitioner stated she was unable to visit a doctor until October 21, 2013. *Id*. at ¶ 9.

Petitioner stated that over the next two months she received several cortisone shots and attended multiple physical therapy sessions. *Id*. at ¶¶ 10-13. Petitioner explained that she "was diagnosed with a frozen shoulder and inflammation from the flu shot." *Id*. at ¶ 11. Petitioner also described that after additional testing she "underwent surgery for a left shoulder impingement with rotator cuff." *Id*. at ¶ 12. Additionally, petitioner stated that beginning in November 2013, she began to experience pain and achiness all over her body. *Id*. at ¶ 14. The pain led petitioner to undergo steroid therapy and additional medical testing. *Id*. at ¶ 15. Petitioner stated that while the "prednisone therapy did provide some relief," anytime the dosage was lowered the symptoms would worsen. *Id*. at ¶ 16.

Petitioner stated that in the fall of 2014 she began methotrexate therapy to help resolve the symptoms. *Id*. at ¶ 17. Petitioner stated at the time of the affidavit in October 2015, she continued to take additional medications for fibromyalgia and did not have the strength to engage in usual activities and had to endure side effects from the medications. *Id*. at ¶¶ 18-19. Petitioner stated that between November 2013 and May 2014 she was unable to work due to the pain in her arm and the rehabilitation from the surgery. *Id*. at ¶ 21. Petitioner explained that in June 2015, she had to take a leave of absence from work to deal with the arm pain and the side effects from the medication. *Id*. at ¶ 22.

III. Expert Opinions Regarding Vaccine Causation

a. Petitioner's Expert Reports

1. Eric Gershwin, M.D., M.AC.P., M.A.C.R.

Petitioner submitted two expert reports by Dr. Eric Gershwin, an immunologist, to provide an opinion on vaccine causation. Pet. Ex. 8 (ECF No. 33); Pet. Ex. 9 (ECF No. 54). Dr. Gershwin reviewed petitioner's medical records and wrote, "I believe that Ms. Allen did suffer a local inflammatory response to the vaccine and that this was severe, is consistent with the elevation of inflammatory markers, and led to the requirement for shoulder surgery." Pet. Ex. 8 at 2.

Dr. Gershwin explained that "shoulder injuries, and indeed local reactions following vaccine administrations, are extremely common." Pet. Ex. 8 at 2. Dr. Gershwin explained, "…regional lymph nodes engulf the vaccine antigen and begin the process of antigen presentation and ultimately an immune response…on occasion, these can lead to a significant local inflammatory response," and result in "a variety of shoulder injuries…such as shoulder dysfunction, frozen shoulder and adhesive capsulitis." Pet. Ex 8 at 2. He stated, "although some local vaccine reactions are due to a direct shoulder injury, in this case, it appears to be that of an immune response, i.e. there is no evidence that the needle directly impacted the shoulder." *Id.* at 2. Dr. Gershwin cited to the *Atanasoff et. al.*, article and stated that mechanism of injury is well described in the literature.[8] *Id*.

Dr. Gershwin also stated that petitioner's elevation of her sedimentation rate and CRP "are all consistent with an inflammatory response to the vaccine." *Id.* He observed that petitioner reported erythema, pain, swelling and stiffness in her left shoulder and stated that, "these are all signs of inflammation." *Id.* at 1. He also stated that petitioner's November 2013 MRI findings were consistent with inflammation, and opined that petitioner, "did suffer a local inflammatory response to the vaccine," that was severe and "consistent with the elevation of inflammatory marker, [it] led to the requirement for shoulder surgery." *Id*. at 2.

In his second report, in response to the Court's order and Dr. Schroeder's expert report, Dr. Gershwin stated that "there is evidence intradermal vaccines can cause a systemic inflammatory response." Pet. Ex. 9 at 2. First, Dr. Gershwin observed that the intradermal injection needle is only 1.5 mm long, but stated that, "intradermal injections are actually difficult [to administer] and lead to local bleeding and, not uncommonly, become subcutaneous injections." *Id.* at 1. He also stated that "systemic reactions to allergy skin tests have been known for decades and can even lead to anaphylaxis, i.e. an intradermal injection is more than just a local injection." *Id.* at 2.

Dr. Gershwin referenced the article by *Rosenbaum et. al*., in which "the authors documented that even though the injection was intradermal, there was evidence of systemic inflammation confirmed by molecular signatures, including the upregulation of IL-6 and TNF

[8] Atanasoff, S. et al., *Shoulder injury related to vaccine administration (SIRVA),* 28 Vaccine 8049-52 (2010). [Resp. Ex. D, Tab 2].

and acute phase response signaling."[9] Pet. Ex. 9 at 2; Pet. Ex. 9-E. The authors of the study sought to better understand early systemic changes, including changes at the site of injection which are responsible for a protective immune response generated by the intradermal injection of a modified Ankara vaccine. Pet. Ex. 9-E at 1. The authors explained that "skin is an ideal target for vaccine injection due to the diversity of resident and recruited immune cells, including macrophages, Langerhans cells, and several subsets of dermal dendritic cells." *Id.* at 2. They commented that there are many advantages to administering vaccines into the skin, but that the "intradermal route remains rarely used in the medical field due to the lack of reliability of the immunization technique." *Id.* The authors found "a strong early local and systemic inflammatory response that peaked at 24 hours post-vaccination, which was then progressively replaced by an adaptive response." *Id.* They documented that the "local innate response was characterized by early massive recruitment of granulocytes, macrophages, and monocytoid cells." *Id.* at 10. Further, they noted that the "innate response was also initiated at the systemic level with rapid and transient granulocyte recruitment and the release of multiple inflammatory cytokines including IL-1β, IL-6 and TNFα among others from six to 24 hours post-injection, followed by a persistent phase involving inflammatory monocytes." *Id.*

Dr. Gershwin concluded his second report stating, "not only can an intradermal vaccination induce an immune response, but it can clearly cause a local inflammatory reaction and injury that Ms. Allen suffered in her shoulder." *Id*.

2. Steven R. Graboff, M.D.

Petitioner submitted two expert reports from Dr. Steven R. Graboff, an orthopedic surgeon. Pet. Ex. 11 (ECF No. 71); Pet. Ex. 12 (ECF No. 80). Dr. Graboff reviewed petitioner's medical records and affidavit of petitioner and wrote, "orthopedically, this is a classic case of post injection inflammatory response leading to protected movement of the shoulder which is a well-known etiology and cause of the development of adhesive capsulitis (frozen shoulder)." Pet. Ex. 11 at 4. He also stated that, "the adhesive capsulitis (frozen shoulder) was directly and proximately caused in the left shoulder by the inflammatory pain from the vaccination given to her on October 1, 2013." *Id*. at 3.

During petitioner's shoulder surgery on January 7, 2014, the preoperative note indicated that she suffered from adhesive capsulitis as adhesions were noted to be released in the left shoulder during the manipulation under anesthesia. Pet. Ex. 11 at 4. Dr. Graboff stated that petitioner's development of adhesive capsulitis was "objectively proven to be present in [petitioner], not only based on clinical findings and subjective complaints, but during the operation performed on January 7, 2014." *Id.* He stated that the development of petitioner's adhesive capsulitis "occurred during a reasonable time period and the timing indeed makes sense and is well documented in the medical records starting within days of the shoulder injection." *Id.*

Dr. Graboff stated that, "pain, protective behavior, lack of movement and lack of use of an upper extremity is a well-known orthopedic cause for the development of adhesive capsulitis

[9] Rosenbaum, et. al., *Molecular and Cellular Dynamics in the Skin, the Lymph Nodes, and the Blood of the Immune Response to Intradermal Injection of Modified Vaccinia Ankara Vaccine*, 9 Frontiers of Immunology 87 (2018). [Pet. Ex. 9, Tab E].

and frozen shoulder." *Id.* at 4. Further he stated, "any pain-inducing event such as a painful vaccination can set this cycle into effect leading to the development of adhesive capsulitis and frozen shoulder as a result of the pain and inflammation and lack of use of the extremity because of the discomfort." *Id.* He explained that "the manipulation under anesthesia was performed, however, because she had a loss of full range of motion of her shoulder associated with pain, which by simple definition is that of a frozen shoulder/adhesive capsulitis." *Id.* Dr. Graboff opined that all of the medical care and treatment that petitioner received after the October 1, 2013, vaccination, were "medically indicated, necessary and reasonable and was directly and proximately caused as a result of the vaccination induced inflammatory response causing left shoulder adhesive capsulitis." *Id*.

Finally, Dr. Graboff responded to respondent's expert, Dr. Cagle's contention that petitioner did not have frozen shoulder but underlying rotator cuff pathology. Pet. Ex. 12. at 2. Dr. Graboff wrote, "The actual diagnosis is not in question….[Petitioner] was diagnosed with adhesive capsulitis at the Lahey Clinic on a number of occasions prior to her surgery." *Id.* at 1. He stated, "In this case….the injection occurred in the area of the shoulder with the resultant inflammatory, painful reaction causing limitation of movement of the shoulder, which is a well-known and well-established etiology and pathogenesis for the development of frozen shoulder and adhesive capsulitis that is simply basic training to orthopedic residents during their period of education." *Id.* Dr. Graboff also argued that during petitioner's shoulder surgery, Dr. Smiley noted the audible lysis of lesions on closed manipulation of the shoulder under anesthesia which is by definition would be consistent with frozen shoulder/adhesive capsulitis. *Id.* at 2. Additionally, he observed that petitioner underwent "manipulation under anesthesia" because petitioner had lost full range of motion of her shoulder associated with pain, "which is a well-accepted treatment for adhesive capsulitis and the audible lysis of the lesions confirmed the presence of adhesive capsulitis or frozen shoulder." *Id.*

b. Respondent's Expert Reports

1. Harry W. Schroeder, Jr., M.D., Ph.D.

Respondent submitted two expert reports from immunologist, Dr. Harry W. Schroeder, Jr., M.D., Ph.D., Resp. Ex. A (ECF No. 37); Resp. Ex. C (ECF No. 60). Dr. Schroeder stated that, "induration, erythema and pain at the site of vaccination was quickly attributed to the administration of the Fluzone. However, it is less clear when and how the patient's symptoms of left shoulder pain, and then generalized arthropathy, chronic pain, and point tenderness were attributed to the vaccine." Resp. Ex. A at 6.

Dr. Schroeder explained that the Fluzone Intradermal Quadrivalent vaccine is administered with a microinjection system. Resp. Ex. A at 8. He explained that "the skin has been recognized as a potentially excellent site for vaccination. It is easily accessible and has both cellular and humoral immune system components." *Id.* Dr. Schroeder stated that microinjection system uses a "tiny hollow microneedle that penetrates 1.5 mm into the skin from the outer skin surface to deliver a volume in the range of 100-200 µl." *Id.* Citing to the Fluzone Quadrivalent package insert ("package insert"), Dr. Schroeder stated that, "in adults 18 through 64 years of age, the most common injection site reactions were pain (53.3%), pruritus (52.1%),

erythema (36.7%), swelling (19.5%), and induration (17.0%)." Resp. Ex. A at 9; Resp. Ex. A, Tab 374, 37-5. He stated, "I find it quite plausible that the vaccine was the proximate cause of the local induration, erythema, edema, and pain at the site of injection," as it is a recognized adverse reaction. Resp. Ex. A at 10. However, he asserted that, "The fact the vaccine was administered intradermally rules out the proposed causal mechanism of needle entry into the joint and/or bursa of the vaccine into the left shoulder." *Id.*

In his second expert report he opined that petitioner's local inflammatory response resulted in what he calls "symptom complex #1." Resp. Ex. C at 1. He opined that petitioner then developed "symptom complex #2," with pain in her left shoulder. *Id*. Dr. Schroeder opined that this was "associated with a tear in one of the tendons in the shoulder and responded to surgical correction, with no further pain after the surgery." *Id*.

Dr. Schroeder agreed with Dr. Gershwin that the "initial impression of an inflammatory arthritis led to the patient being treated more aggressively than what would normally be warranted for fibromyalgia." *Id*. He ultimately argued that petitioner did suffer from a local surface reaction to the vaccine, but the polyarthralgias and chronic pain that developed six months later were not caused by the vaccine. *Id*. at 11.

2. Paul J. Cagle, M.D.

Respondent submitted expert reports from Dr. Paul J. Cagle, M.D., an orthopaedic surgeon. Resp. Ex. D (ECF No. 72); Resp. Ex. F (ECF No. 79). In his first report, Dr. Cagle stated that the findings associated with the shoulder pain in petitioner's case are not connected with the vaccination and were not caused by the vaccination. Resp. Ex. D at 7-8.

Dr. Cagle asserted that even if petitioner reported her left shoulder pain began immediately after the vaccination, she did not seek medical attention for her left shoulder injury for several weeks. Resp. Ex. D at 5. He also stated that petitioner's MRI was inconsistent with SIRVA. *Id.* He wrote that her MRI showed "a tiny pinpoint full-thickness perforation of the distal supraspinatus tendon, a degenerative tear of the anterior glenoid labrum, a small amount of fluid in the subdeltoid bursa and no signs of adhesive capsulitis," and that these findings were "…in complete contrast to the SIRVA literature." *Id.*

Dr. Cagle also addressed whether the intradermal needle could have cause the "tiny rotator cuff tear," and concluded that "[r]egardless of technique, there is no conceivable way for an intradermal needle, which is 1.5 mm or 0.05 inches, to have reached the depth of the rotator cuff. Therefore, it is impossible for the intradermal need[le] to have caused the tiny perforation in the supraspinatus tendon." Pet. Ex. D at 6.

Dr. Cagle asserted that the January 7, 2020, operative note does not support a diagnosis of adhesive capsulitis because it does not document "visualized adhesive capsulitis" or "need for a lysis of adhesion." Resp. Ex. D at 3, 6-7. Dr. Cagle explained that "although there was a mention of an audible sound during the operation, this is simply not support[ed] by the remaining operative note and is not mentioned as a diagnosis by subsequent clinical notes." *Id*. at 7. He argued that since Dr. Smiley, the operating physician, did not provide a diagnosis of adhesive

capsulitis in the operative report, it was not encountered during the procedure. *Id*. at 6. Dr. Cagle also argued that the operative note did not document "thickened capsules" or "need for capsular release." *Id*. at 6-7.

Dr. Cagle described adhesive capsulitis as "a shoulder condition causing pain and decreased range of motion…[t]he condition causes inflammation and thickening of the shoulder joint capsule. This thickening is a hallmark of the disease process and is what causes the shoulder to be less mobile. Thus, the diagnosis of adhesive capsulitis is made when a patient present[s] with loss of range of motion." Resp. Ex. F at 2. He then goes on to explain the technique of shoulder manipulation under anesthesia, as was performed in this case. *Id*. at 2-3. Dr. Cagle discussed that while he has "no doubt that a sound was heard…there is nothing about hearing the documented sound that would confirm or deny the successful release of a thick and inflamed capsule." *Id*. at 3.

Dr. Cagle referenced the operative report which noted that Dr. Smiley placed the arthroscope into the subacromial space and appreciated "hypertrophic synovium," which in Dr. Cagle's medical opinion is "not equivalent to a thickened shoulder capsule, and a finding of hypertrophic synovium absolutely does not support the diagnosis of adhesive capsulitis." Resp. Ex. F at 3-4. Dr. Cagle concluded that petitioner did not have adhesive capsulitis. *Id*. at 4.

Dr. Cagle recognized that many people in petitioner's age group can have asymptomatic tears of the rotator cuff. Resp. Ex. D at 7. He goes on to describe that the best summary of petitioner's case was provided by Dr. Robert Duncan on May 20, 2015, "Dr. Duncan reports that she underwent a shoulder arthroscopy and the tear that was repaired was likely incidentally visualized." *Id*.

Dr. Cagle concluded that "the definition of SIRVA is not met by timing as there is no medical documentation providing an association with 48 hours and a direct causal relationship is not established." Resp. Ex. D at 7.

IV. Legal Standard for Adjudication

To receive compensation through the Program, petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that she suffered an injury that was actually caused by a vaccination. *See* §§ 300aa-13(a)(1)(A), 11(c)(1); *Capizzano v. Sec'y of Health & Human Servs.,* 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner does not allege that she suffered a Table Injury, she must prove that a vaccine she received caused her injury. To do so, she must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and her injury ("*Althen* Prong One"); (2) a logical sequence of cause and effect showing that the vaccine was the reason for her injury ("*Althen* Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and her injury ("*Althen* Prong Three"). § 13(a)(1); *Althen v. Sec'y of Health & Hum. Servs*., 418 F. 3d 1274, 1278 (Fed. Cir. 2005).

Petitioner's burden of proof is by a preponderance of the evidence. § 13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315,

1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.,* 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioner must prove that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *see also Pafford v. Sec'y of Health & Hum. Servs.,* 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Recently, in *Kottenstette,* the Federal Circuit reiterated that proof of causation does not "require identification and proof of specific biological mechanisms[.]" *Kottenstette v. Sec'y of Health & Hum. Servs.,* -- Fed.Appx.—(Fed. Cir. June 15, 2021) (citing *Knudsen v. Sec'y of Health & Hum. Servs.,* 35 F.3d 543, 549 (Fed. Cir. 1994). Causation "can be found in vaccine cases….without detailed medical and scientific exposition of the biological mechanisms." *Knudsen,* 35 F.3d 543, 548-49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the petitioner's injury, as long as the petitioner can show by a preponderance of evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be. *Moberly v. Sec'y of Health & Hum. Servs.,* 592 F.3d 1315, 1325 (Fed. Cir. 2010).

Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in his favor. *See Moberly*, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); *Althen*, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

In Vaccine Act cases, expert testimony may be evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993); *see also Cedillo*, 617 F.3d at 1339 (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). In Vaccine Program cases, the *Daubert* analysis has been used in the weighing of the scientific evidence actually proffered and heard rather than as a tool for the pre-trial exclusion of expert testimony. *Davis v. Sec'y of Health & Hum. Servs.,* 94 Fed. Cl. 53, 66–67 (Fed. Cl. 2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"), *aff'd*, 420 F. App'x 923 (Fed. Cir. 2011). The flexible use of the *Daubert* factors to determine the persuasiveness and/or reliability of expert testimony in Vaccine

Program cases has routinely been upheld. *See, e.g.*, *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 742–45 (2009).

Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1362 (Fed. Cir. 2000)). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder,* 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner,* 522 U.S. 146 (1997)). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly,* 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280 (holding that Congress created a system in which "close calls regarding causation are resolved in favor of injured claimants"); *Knudsen*, 35 F.3d at 551 ("If the evidence (on alternative cause) is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded.").

V. Finding of Fact regarding Nature of Petitioner's Injury

The first issue to be resolved is petitioner's diagnosis. The respondent disputed petitioner's diagnosis of adhesive capsulitis. *See* Resp. Response at 12-15. Petitioner asserted that she developed adhesive capsulitis post-vaccination that required surgical intervention. Pet. Mot. at 13-14.

a. Legal standard

The Vaccine Act provides that Special Masters are to consider any medical diagnosis contained in the record. §300aa-13(b)(1). A Special Master must weigh and evaluate opposing expert opinions, medical and scientific evidence, and the evidentiary record in deciding whether petitioners' have met their burden of proof. *Id.* The function of a special master is not to 'diagnose' vaccine-related injuries, but instead to determine based on the evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the petitioner's injury. *Lombardi v. Sec. of Health & Human Servs.,* 656 F.3d 1343, 1351 (citing *Andreu,* 569 F.3d at 1382) (Fed. Cir. 2011). In *Capizzano,* the Federal Circuit provided additional guidance as how special masters should weigh evidence, placing emphasis on the statements of treating doctors. 440 F.3d at 1320 (Fed. Cir. 2006). The Federal Circuit stated, "*Althen III* explained that medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a

'logical sequence of cause and effect' shows that the vaccination was the reason for the injury.'" *Capizzano* at 1326 (quoting *Althen,* F. 3d at 1280).

Additionally, medical records are generally considered trustworthy. *See Cucuras v. Sec'y of Health & Human Servs.,* 993 F. 2d at 1525, 1528 (Fed. Cir. 1993). Where medical records are clear, consistent, and complete, they should be afforded substantial weight. *See Lowrie v. Sec'y of Health & Human Servs.,* No. 03-1585V, 2005 WL 6117475 (Fed. Cl. Spec. Mstr., Dec. 12, 2005). Medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Human Servs.,* 42 Fed. Cl. at 381, 391 (1998).

If there is a dispute as to the nature of the petitioner's injury, the special master may opine on the nature of the petitioner's injury." *Contreras v. Sec'y of Health & Human Servs.,* 844 F. 3d 1363, 1368 (Fed. Cir. 2017) (citing *Hibbard v. Sec'y of Health & Human Servs.,* 686 F. 3d 1355 (Fed. Cir. 2012); *see also Broekelschen v. Sec'y of Health & Human Servs.,* 618, F.3d 1339 at 1346 (Fed. Cir. 2010). In *Broeklschen,* the Federal Circuit stated that it was appropriate for the special master to first determine which injury is best supported by the evidence presented in the record before applying the *Althen* test. *Broekelschen* at 1346.

In this case, respondent argued that petitioner has not demonstrated a "medically recognized injury to be compensated." Resp. Response at 12. Specifically, respondent argued that petitioner has not demonstrated that she suffered from adhesive capsulitis of the left shoulder, and instead asserted that petitioner's left shoulder symptoms "are consistent with a diagnosis of a rotator cuff tear." *Id.* at 15. Petitioner argued that her injury is adhesive capsulitis, which is a cognizable injury post-vaccination. Pet. Reply at 1. As such, it is necessary to determine petitioner's injury.

b. Adhesive Capsulitis and adhesive capsulitis post-vaccination

Adhesive capsulitis is chronic inflammation of the capsule sub-synovial layer, which produces capsular thickening, fibrosis, and adherence of the capsule to itself and to the anatomic neck of the humerus.[10] Resp. Ex. D-32. The article by *Neviaser* described adhesive capsulitis as, "painful, gradual loss of active and passive shoulder motion." Resp. Ex. D-32 at 1. Adhesive capsulitis is also sometimes diagnosed as "frozen shoulder." *Id.* at 2. It is characterized by a "thickened, tight glenohumeral joint capsule with adhesions obliterating the normally patulous axillary fold." *Id.* Patients often present with pain of insidious onset and the onset of symptoms tends to be more gradual than in other shoulder conditions. *Id.* Further, patients experience loss of motion that accompanies the pain and patients have described difficulty dressing, combing their hair, or reaching to their back. *Id.* at 3.

Treatment of adhesive capsulitis includes physical therapy that includes gentle and progressive stretching. *Id.* Additionally, the *Neviaser* article noted that while intra-articular steroid injections hold "promise" they often only provide transient reduction in pain, with no

[10] Andrew S. Neviaser & Robert J. Neviaser, *Adhesive Capsulitis of the Shoulder*, 19 J. Am. Acad. Orthop. Surg., 536-542 (2011). [Resp. Ex. D-32].

improvement to motion. *Id.* If physical therapy does not improve the symptoms of a patient with adhesive capsulitis, surgical interventions are considered. *Id.* at 4. There are two types of surgical intervention, manipulation under anesthesia or arthroscopic capsular release. *Id.*

Adhesive capsulitis or frozen shoulder is a common diagnosis that is identified in patients' medical records associated with vaccine-related shoulder dysfunction. For example, in the article by *Bodor*, one patient was diagnosed with adhesive capsulitis after receiving a pneumococcal vaccine injection.[11] Resp. Ex. D, Tab 9 at 1. The article by *Saleh et al.*, submitted by the respondent, documents three cases of adhesive capsulitis post-vaccination.[12] Resp. Ex. D, Tab 11. In the *Saleh* article, the three patients reported severe arm pain soon after receiving a vaccination and the pain was accompanied by decrease range of motion. *Id.* at 1-3. Another article by *Degreef*, also submitted by respondent, documented three cases of "frozen shoulder" post-vaccination.[13] Resp. Ex. D, Tab 17. In the *Degreef* article, the authors explained that the three patients mentioned pain post-vaccination, followed by progressively decreasing shoulder mobility. *Id.* at 3.

Finally, when respondent proposed adding SIRVA to the Vaccine Injury Table, respondent explained, "The IOM reviewed the scientific and medical literature finding evidence that convincingly supports a causal relationship between vaccine injection (with a needle) into an arm and deltoid bursitis….The VICP case series (referencing the *Atanasoff* article) found several diagnoses, beyond deltoid bursitis, that resulted in shoulder pain following vaccination, including tendonitis, impingement syndrome, frozen shoulder syndrome, and adhesive capsulitis." *Notice of Proposed Rulemaking,* 80 FR 45132-01, 2015 WL 4538923 (2015).

c. Respondent's argument regarding petitioner's diagnosis

Respondent argued that petitioner had failed to demonstrate a "medically recognized injury to be compensated." Resp. Response at 12. Specifically, respondent argued that petitioner had not demonstrated that she suffered from adhesive capsulitis. *Id.* at 13. He argued that adhesive capsulitis causes inflammation and thickening of the shoulder joint capsule and that "this thickening is the hallmark of the disease process and what causes the shoulder to be less mobile." Resp. Ex. F at 2. Dr. Cagle explained in his expert report that there are three ways to treat adhesive capsulitis – non surgically through physical therapy, manipulation under anesthesia, or an arthroscopic capsular release. Resp. Ex. F at 3. Dr. Cagle noted that all operative reports have a pre-operative diagnosis, and a post-operative diagnosis, and in petitioner's case a diagnosis of adhesive capsulitis was not noted in the post-operative report, meaning that Dr. Smiley "did not actually encounter adhesive capsulitis during the procedure." Resp. Ex. D at 6.

[11] Bodor, M. & Montalvo, E., *Vaccination-related shoulder dysfunction,* 25 Vaccine 585-587 (2007). [Resp. Ex. D, Tab 9].

[12] Zeina M. Saleh, et. al., *Onset of Frozen Shoulder Following Pneumococcal and Influenza Vaccinations,* 14 J. of Chiropractic Med., 285-289 (2015). [Resp. Ex. D-11].

[13] Degreef, I. & Debeer, Ph., *Post-vaccination Frozen Shoulder Syndrome. Report of 3 cases,* 112 Act. Chir. Belg. 447-49 (2012). [Resp. Ex. D, Tab 17].

Dr. Cagle asserted that the operative note from petitioner's January 7, 2014, surgery does not support a diagnosis of adhesive capsulitis because it does not document "visualized adhesive capsulitis" or "need for a lysis of adhesion". Resp. Ex. D at 3, 6-7. Dr. Cagle also asserted that the operative note does not document "thickened capsules" or "need for… a capsular release". Resp. Ex. D at 3, 6-7. Dr. Cagle explained that petitioner underwent a manipulation under anesthesia or an arthroscopic capsular release, and the operative report written by Dr. Smiley following the procedure summarized all findings. Resp. Ex. F at 3. Dr. Cagle explained that while Dr. Smiley heard a sound, if that sound was the shoulder capsule rupturing during the MUA, there would have been physical manifestations of blood, confirmation of the adhesions, or the arthroscope would have observed the rupture of the thickened tissues – instead Dr. Cagle explained that none of that information was listed in Dr. Smiley's post-operative report, ruling out the confirmatory diagnosis of adhesive capsulitis. Resp. Ex. F at 3.

In the alternative, Dr. Cagle asserted that petitioner's diagnosis is more consistent with a rotator cuff tear, which he noted was also diagnosed by petitioner's orthopedists, Dr. McLaughlin, and Dr. Smiley. *See* Pet. Ex. 7; Pet. Ex. 5 at 102; Pet. Ex 6 at 7. Dr. Cagle argued that the diagnosis of rotator cuff tear is supported by the medical records as it was seen on petitioner's MRI, visualized during the operation, and is common pathway for shoulder pain in petitioner's age group. Resp. Response at 15; Resp. Ex. D at 7.

Respondent suggested that petitioner's left shoulder MRI done on November 17, 2013, forty-seven days after the vaccination, showed no signs of adhesive capsulitis. Resp. Ex. D at 5. Therefore, Dr. Cagle argued that Dr. Graboff's argument of a diagnosis of adhesive capsulitis does not align with the medical records as the purported local reaction had already resolved. *Id*.

Respondent also argued that petitioner's orthopedic expert, Dr. Graboff, provided no support in the form of medical literature for his assertion that petitioner has a "classic case of post injection inflammatory response leading to protected movement of the shoulder which is a well-known etiology and cause of the development of adhesive capsulitis (frozen shoulder)." Resp. Ex. D at 6. Respondent cited to *Moberly*, that accepting Dr. Graboff's theory without literature support as a supposition or mere possibility are "insufficient to meet petitioner's burden." Resp. Response at 16; *See Moberly*, 592 F.3d at 1322-24.

Respondent concluded that petitioner has not offered preponderantly reputable or reliable evidence to support her contention that the intradermal flu vaccine can cause adhesive capsulitis. *Id*. at 17.

d. Petitioner's argument in support of the diagnosis of adhesive capsulitis

Petitioner's experts, Drs. Gershwin and Graboff argued that the intradermal flu vaccine caused a robust local inflammatory response, causing pain protective behavior that resulted in adhesive capsulitis. Pet. Mot. at 8; Pet. Reply at 1-2.

Petitioner argued that the medical records, expert reports, and the treating physicians directly indicate that petitioner suffered from adhesive capsulitis. Pet. Reply at 1. On November 19, 2013, petitioner was seen at North Shore Shoulder complaining she "feels that the stiffness in her shoulder is getting worse." Pet. Reply at 1; Pet. Ex. 13; Pet. Ex. 6 at 4-5. Dr. McLaughlin's

impression indicated that it "does appear she is beginning to develop a picture of early frozen shoulder." Pet. Ex. 6 at 4-5.

On December 3, 2013, Dr. McLaughlin noted that the "MRI of her shoulder shows no obvious full-thickness rotator cuff tear…and she is suffering from what appears to be early and intense frozen shoulder of her left shoulder." Pet. Ex. 6 at 5. Dr. Graboff stated that the post injection inflammatory response explained by Dr. Gershwin was directly connected to the adhesive capsulitis. Pet. Ex. 11 at 3-4. In his second expert report, Dr. Graboff stated that "[petitioner] was diagnosed with adhesive capsulitis (frozen shoulder) at the Lahey Clinic on a number of occasions prior to her surgery, January 7, 2014, including notations [from] December 16, 2013, and December 23, 2013." Pet. Ex. 12 at 1.

Dr. Graboff observed that at the appointment on December 16, 2013, Dr. Katz noted that following the MRI in November 2013, which showed some tears, the doctors did not feel that surgery was needed and instead opted for "aggressive physical therapy." Pet. Ex. 5 at 74. Petitioner said that the "physical therapy made things worse," and Dr. Katz stated that "by this time she has developed somewhat of an adhesive capsulitis [in her] left shoulder." *Id*. On December 23, 2013, petitioner saw her PCP, Dr. Khan, and said that "over the last 24 to 36 hours, the pain has returned. It is quite excruciating. [Petitioner] is quite weary and upset about this continued condition." Pet. Ex. 5 at 72. It further noted that petitioner "is strong in the rotator cuff." *Id*. On December 25, 2013, Dr. Katz noted "she saw range of motion of abduction of the left shoulder with some adhesive capsulitis." Pet. Ex. 5 at 76-77.

Dr. Graboff asserted that the petitioner's pre-operative surgical note included adhesive capsulitis, and was objectively proven during the surgery. Pet. Ex. 11 at 4; Pet. Ex. 5 at 102-103. Petitioner argued that while the adhesions may not have been visualized, Dr. Smiley specifically noted the audible lysis of the adhesions on closed manipulation under general anesthesia before he opened the shoulder. *See* Pet. Ex. 5 at 102-103. Dr. Graboff explained that "not all patients have visualized adhesions or thickened capsule during arthroscopic evaluation…especially those patients who have undergone a manipulation under anesthesia…this is not an 'all or none' situation and there are various degrees of pathology resulting in the condition." Pet. Ex. 12 at 2.

In his second report, Dr. Graboff conceded that, "the medical records clearly show that there were findings of a rotator cuff tear, but also clearly documents in numerous locations that there was adhesive capsulitis/frozen shoulder." Pet. Ex. 12 at 2. He also explained that "there is absolutely no evidence that the tiny rotator cuff tear, which was incidentally found, would have required any type of medical or surgical care whatsoever." *Id*.

Finally, petitioner argued that "the intradermal vaccination caused inflammation and pain leading to pain protective behavior…leading to adhesive capsulitis. The adhesive capsulitis (frozen shoulder) was directly and proximately caused in the left shoulder by the inflammatory pain from the vaccination given to her on October 1, 2013." Pet. Ex. 11 at 4. Dr. Graboff opined that "orthopedically, this is a classic case of post injection inflammatory response leading to protected movement of the shoulder which is a well-known etiology and cause of the development of adhesive capsulitis (frozen shoulder)." Pet. Ex. 11 at 4. He also stated that, "the

adhesive capsulitis (frozen shoulder) was directly and proximately caused in the left shoulder by the inflammatory pain from the vaccination given to her on October 1, 2013." *Id*. at 3.

e. Discussion and conclusion of petitioner's diagnosis of adhesive capsulitis

Petitioner argued that her diagnosis of adhesive capsulitis is correct based on the sequence of events that started directly after the October 1, 2013, flu vaccination, including an inflammatory response that resulted in pain protective behavior and ultimately adhesive capsulitis. Pet. Mot. at 6. Respondent argued that it is more likely that petitioner's symptoms are consistent with a diagnosis of rotator cuff tear, and do not endorse a theory of adhesive capsulitis based on the record as a whole. Resp. Response at 12-15. Petitioner has demonstrated by preponderant evidence that she suffered adhesive capsulitis after receiving the intradermal flu vaccine on October 1, 2013. Petitioner's medical records, expert reports, and medical literature support the diagnosis of adhesive capsulitis.

Petitioner's treating physicians consistently noted that petitioner's symptoms of inflammation, pain, and redness started at or around two days post vaccination. *See* Pet. Ex. 4 at 1; Pet. Ex 5 at 63, 66, 74; Pet. Ex. 6 at 6. For example, on November 19, 2013, Dr. McLaughlin opined that petitioner had developed "a picture of early frozen shoulder" and noted that petitioner had "increasing pain and stiffness." Pet. Ex. 15 at 3-4. On December 3, 2013, at a follow-up appointment with Dr. McLaughlin, he reiterated the diagnosis of frozen shoulder, stating that petitioner had "early and intense frozen shoulder of her left shoulder." *Id.* at 5. When petitioner met with rheumatologist, Dr. Katz on December 16, 2013, Dr. Katz noted that petitioner received a flu vaccine in her left shoulder in October and that she had undergone physical therapy and injections since that time, but "by this time she has developed somewhat of an adhesive capsulitis [of the] left shoulder." Pet. Ex. 5 at 77. Additionally, Dr. Katz noted during the physical examination that petitioner had a "range of motion of abduction of the left shoulder with some adhesive capsulitis." *Id.* at 76.

In addition to the diagnosis of adhesive capsulitis or frozen shoulder appearing in the medical records, petitioner's clinical signs and symptoms, along with treatment were consistent with adhesive capsulitis described in the medical literature submitted in this case. The article by *Saleh et al*., explains that "the diagnosis of frozen shoulder (adhesive capsulitis) is made by the clinical presentation of shoulder stiffness and pain." Resp. Ex. D, Tab 11 at 3. The *Neviaser* article also explained that "a mechanical restraint to passive motion is the hallmark of adhesive capsulitis. This finding is best appreciated on passive external rotation with the arm at the side." Resp. Ex. D, Tab 32 at 3. Further, the article stated that a patient will usually have normal rotator cuff strength. *Id.* The *Neviaser* article described patients with adhesive capsulitis will have loss of motion that accompanies the pain and patients have difficulty dressing, combing their hair, and reaching behind their back. *Id.*

Petitioner noted stiffness in her left shoulder as early as three days after the vaccination in question. At her first medical appointment on October 21, 2013, petitioner demonstrated "decreased range of motion in the shoulder in all directions and secondary to pain." Pet. Ex. 5 at 65. When petitioner sought treatment from orthopedist, Dr. McLaughlin, on October 29, 2013, petitioner complained of pain and stiffness of the left shoulder. Pet. Ex. 15 at 1. The stiffness

continued when she saw Dr. McLaughlin again on November 19, 2013. *Id.* at 4. Further, her physical examination showed reduced range of motion, as she demonstrated "passive abduction 130 rotation, external 20," with "pain in extremes of range of motion," on November 19, 2013. Pet. Ex. 6 at 3. She also demonstrated "passive external rotation 15 and passive forward flexion 120 with discomfort at terminal range of motion." *Id*. at 5. When petitioner went to the emergency department on December 1, 2013, petitioner had "decreased range of motion secondary to discomfort." Pet. Ex. 7 at 6.

The *Neviaser* and *Saleh* articles also explain that treatment for adhesive capsulitis can range from conservative treatment, such as physical therapy and the use of non-steroid anti-inflammatory drugs, to intra-articular steroid injections and finally, surgical intervention. Resp. Ex. D, Tab 32 at 4; Resp. Ex. D, Tab 11 at 3-4. Here, petitioner was initially prescribed physical therapy, as well as non-steroid anti-inflammatories and Tylenol with Codeine. Pet. Ex. 6 at 3. But by December 2013 petitioner explained that the physical therapy was making her symptoms worse and was instructed to "stop therapy for the next 2 weeks." *Id*. at 5-6. Additionally, petitioner received two cortisone injections on October 29, 2013, and December 6, 2013, for treatment of her shoulder. *See* Pet. Ex. 6 at 2; Pet. Ex. 5 at 86. Eventually, petitioner elected to have surgical intervention because physical therapy and the steroid injections were not providing consistent pain relief.

While Dr. Cagle argued that adhesive capsulitis was not in the pre-or-post operative note, the manipulation under anesthesia that Dr. Smiley performed is done specifically to address adhesive capsulitis and the audible lysis of the lesions is entirely consistent with that diagnosis. The operative note stated, "Left shoulder was manipulated. Next, 20 degrees of abduction was obtained with audible lysis of lesions." Resp. Ex. D at 7. The *Neviaser* article explained, "manipulation under anesthesia was the standard of care for the management of refractory adhesive capsulitis." Resp. Ex. D, Tab 32 at 4. The article also explains that during the manipulation, "audible popping of the capsule," can be heard. *Id.* at 5. Petitioner's orthopedic expert, Dr. Graboff also explained that the manipulation under anesthesia would not have been necessary or performed if petitioner had full range of motion in her shoulder. Pet. Ex. 12 at 2. He stated that both the fact that Dr. Smiley performed the manipulation under anesthesia and documented to have found "audible" lysis of adhesions, supports the diagnosis of adhesive capsulitis. *Id.* I agree with Dr. Graboff. Manipulation under anesthesia is a known and accepted treatment for adhesive capsulitis and it would be unlikely that petitioner's surgeon, Dr. Smiley, would have performed closed manipulation of the shoulder if he had not suspected adhesive capsulitis nor is it likely that he would have noted the audible lysis of lesions had he not perceived the disruption of the lesions upon manipulation. While the petitioner also had a minor, at least previously asymptomatic tear of a rotator cuff tendon, the most likely cause of pain relief in this case was the lysis of the lesions that impaired her range of motion in the left arm.

Finally, the presence of rotator cuff tear pathology is consistent with other shoulder injury post-vaccination cases before the program and seems incidental to the acute shoulder pain that petitioner felt following the vaccination at issue. The article by *Saleh et. al.,* submitted by the respondent, described three cases of acute onset of adhesive capsulitis following pneumococcal

and influenza vaccines, both delivered intramuscularly. Resp. Ex. D, Tab 11, at 1.[14] The article stated that while age-related degenerative changes could account for some pain and limitation of motion, when there is "acute onset of these changes and timely association with vaccination, age-related changes were unlikely to be the cause even with radiologic evidence of mild degenerative changes." *Id*. at 2. The *Atanasoff* article also noted that MRI findings in post-vaccination shoulder injury cases, included rotator cuff tears. Resp. Ex. D, Tab 2. The article observed that 39% of individuals past middle age were found to have partial or complete rotator cuff tears that were completely asymptomatic. *Id*. at 2. The authors concluded, "….some of the MRI findings…such as rotator cuff tears, may have been present prior to the vaccination and became symptomatic as a result of vaccination associated with synovial inflammation." *Id*. at 3. In this case, it seems distinctly possible that the minor rotator cuff tear may not have been the source of her pain and dysfunction at all, but was simply co-existent with the primary source of pain and dysfunction generated by the inflammatory response to the vaccine and adhesive capsulitis caused by pain protective behavior in response to that pain.

Petitioner's medical records include a diagnosis of adhesive capsulitis in the multiple appointments following the vaccination, and while petitioner's shoulder surgery did not expressly list "adhesive capsulitis" as a post-operative diagnosis, the note was detailed and descriptive to the procedures and findings consistent with adhesive capsulitis. *See* Pet. Ex. 5 at 102-03. As such, for the reasons discussed above, I find that petitioner developed adhesive capsulitis following her October 1, 2013, intradermal flu vaccination which was the primary source of her pain and dysfunction.

V. Causation Analysis

a. *Althen* Prong One

Under *Althen* prong one, the causation theory must relate to the injury alleged. Thus, a petitioner must provide a "reputable" medical or scientific explanation, demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56. The theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). It must only be "legally probable, not medically or scientifically certain." *Id.* at 549. However, the theory still must be based on a "sound and reliable medical or scientific explanation." *Knudsen* at 548. The Federal Circuit explained in *Althen* that "while [that petitioner's claim] involves the possible link between [tetanus toxoid] vaccination and central nervous system injury, *a sequence hitherto unproven in medicine*, the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field *bereft of complete and direct proof of how vaccines affect the human body." Althen,* 418 F.3d at 1280 (emphasis added).

Petitioner has presented a sound and reliable theory that the intradermal flu vaccine she received on October 1, 2013, caused a robust local inflammatory response, resulting in pain protective behavior, and ultimately adhesive capsulitis. Pet. Ex. 8 at 2.

[14] Zeina M. Saleh, et. al., *Onset of Frozen Shoulder Following Pneumococcal and Influenza Vaccinations,* 14 J. of Chiropractic Med., 285-289 (2015). [Resp. Ex. D-11].

Dr. Gershwin opined that petitioner had both a local reaction and systemic inflammatory response to the vaccination. Pet. Ex. 8 at 2; Pet. Ex. 9 at 2. He stated that petitioner's inflammatory markers, such as sedimentation rate and CRP were elevated, consistent with a "systemic inflammatory response." *Id.* In his second report, Dr. Gershwin stated that "there is evidence that intradermal vaccines can cause a systemic inflammatory response," and observed that while the intradermal injection needle is only 1.5 mm long, the "intradermal injections are actually difficult and lead to local bleeding and, not uncommonly, become subcutaneous injections." Pet. Ex. 9 at 1-2. The *Rosenbuam* article stated that after patients received an intradermal injection there was "evidence of, systemic inflammation confirmed by molecular signatures, including the upregulation of IL-6 and TNF and acute phase response signaling." Pet. Ex. 9-E. The authors found "a strong early local and systemic inflammatory response that peaked at 24 hours post-vaccination, which was then progressively replaced by an adaptive response." *Id.* The authors documented that the "local innate response was characterized by early massive recruitment of granulocytes, macrophages, and monocytoid cells." *Id.* at 10. Further, they noted that the "innate response was also initiated at the systemic level with rapid and transient granulocyte recruitment and the release of multiple inflammatory cytokines including IL-1β,IL-6 and TNFα from six to 24 hours post-injection, followed by a persistent phase involving inflammatory monocytes." *Id.* This article supports petitioner's theory of increased inflammation caused by an intradermal vaccine, and Dr. Gershwin's opinion that the intradermal flu vaccine induced an immune response that caused an inflammatory reaction and injury to petitioner's shoulder.

Respondent's expert, Dr. Schroeder agreed with Dr. Gershwin that petitioner suffered a temporary inflammatory response. Resp. Ex. C at 1. However, he disagreed that petitioner's local inflammatory response could have led to a shoulder injury post-vaccination. Resp. Ex. A at 10. Dr. Schroeder opined that an inflammatory response is expected because "the vaccine is designed to elicit a systemic immune response to influenza antigens that will hopefully provide protection against future infections." Resp. Ex. C at 1. Citing to the Fluzone Quadrivalent package insert, Dr. Schroeder explained that the most common injection site reactions include pain, pruritus, erythema, swelling, and induration, and found "it quite plausible that the vaccine was the proximate cause of the local induration, erythema, edema, and pain at the site of injection," as it is a recognized adverse reaction. Resp. Ex. A at 9-10; Resp. Ex. A, Tab 37-4, 37-5.

Dr. Schroeder's argument that microinjector used for the intradermal flu vaccination could not be the causal mechanism for petitioner's shoulder injury because it was not long enough to enter the joint and/or bursa is not persuasive. He explained that the Fluzone Intradermal Quadrivalent vaccine is administered with a microinjection system. Resp. Ex. A at 8. Dr. Schroeder stated that microinjection system uses a "tiny hollow microneedle that penetrates 1.5 mm into the skin from the outer skin surface to deliver a volume in the range of 100-200 µl." *Id.* He stated that "…the micro-injector system is specifically designed to avoid needle entry into the muscle, much less the joint and/or the bursa beneath." *Id.* at 10. He asserted that, "The fact the vaccine was administered intradermally rules out the proposed causal mechanism of needle entry into the joint and/or bursa of the vaccine into the left shoulder." *Id.* However, Dr. Schroeder's argument misses the point of the petitioner's theory that the

inflammatory response to the vaccine caused significant pain, a response that Dr. Schroeder acknowledged occurs, and that the long standing pain resulted from pain protective behavior causing adhesive capsulitis. Petitioner's theory did not propose that the needle punctured a rotator cuff tendon or a bursa in the shoulder.

The Fluzone Intradermal Patient Information sheet, submitted by respondent, gave an overview of the most common side effects. Resp. Ex. A, Tab 37 at 22-23. The information sheet stated that the most common side effects are, "pain, redness, swelling, hardness, and itching where you get the shot, muscle ache, tiredness, headache, [and] shivering." *Id*. The petitioner experienced a number of these symptoms but also developed a frozen shoulder by limiting her arm motion in response to the pain. As noted above, she does not contend that the shot penetrated structures in the rotator cuff.

The medical literature submitted by respondent also supports petitioner's theory that the intradermal flu vaccination can cause an inflammatory response that results in pain, leading to adhesive capsulitis. The *Meijer et., al.*, article aimed to compare the side effects of intradermal versus intramuscular influenza vaccinations among healthcare workers. Resp. Ex. A Tab 37-2. [15] The study found that "both systemic and local side effects were more prevalent in the i.d. [intradermal] vaccinated compared to the i.m. [intramuscular] vaccinated participants." *Id*. at 5. Additionally, 453 participants who received the intradermal vaccination reported pain, compared to 79 who received an intramuscular vaccination and 62 participants who received the intradermal vaccination reported joint pain, compared to the 14 who reported joint pain following the intramuscular vaccination. *Id.* at 5.

The respondent's argument that petitioner's shoulder pain and dysfunction were caused by her rotator cuff tear is unpersuasive. Dr. Schroeder wrote that, "The patient was found to have an anatomic disorder, a tendon tear; and the symptoms of pain and decreased range of motion completely resolved following surgical correction. Resp. Ex. A at 10. However, as discussed above, the small tear found in her shoulder appeared to be found "incidentally," when Dr. Smiley entered the shoulder arthroscopically after he manipulated the shoulder under anesthesia. Additionally, respondent's expert, Dr. Cagle noted that "multiple studies have demonstrated both through ultrasound assessment and through MRI assessment that people over the age of 50 years old can have asymptomatic tears of the rotator cuff." Resp. Ex. D at 7. The article by *Sher* found that in individuals aged forty to sixty years old, 54% had a tear of the rotator cuff, 28% had a full-thickness tear, and 12% had a partial thickness tear.[16] Resp. Ex. D Tab 33. The authors note that "the tears were increasingly frequent with advanced age." *Id.* Similarly, the *Tempelhof* study found that the prevalence of rotator cuff tears increased significantly with age, with "54% rate of rotator cuff tear among subjects more than 60 years old;

[15] W.J. Meijer, et. al., *Influenza vaccination in healthcare workers; comparison of side effects and preferred route of administration of intradermal versus intramuscular administration,* 35 Vaccine 1517-1523 (2017). [Resp. Ex. A Tab 37-2].

[16] Sher, et. al., *Abnormal Findings on Magnetic Resonance Images of Asymptomatic Shoulders,* 77-A J. of Bone and Joint Surgery (1995). [Resp. Ex. D Tab 33].

28% of them had full-thickness tears and 26% had partial thickness tears."[17] Resp. Ex. D Tab 34. The *Minagawa* study also noted that "asymptomatic rotator cuff tears accounted for 50% of all tears in the 50s but in those older than 60 years of age, the prevalence of asymptomatic rotator cuff tears was significantly greater than that of symptomatic tears."[18] Resp. Ex. D Tab 35.

In this case, petitioner was 61 when she received the flu vaccination and if she had a rotator cuff tear prior to the vaccination, it was asymptomatic, as she did not demonstrate any shoulder pain or dysfunction prior to receiving the vaccination. The January 2014 surgery corrected a small tear of the supraspinatus tendon, in addition to the surgeon performing manipulation. Pet. Ex. 5 at 102-03. Petitioner's orthopedist expert, Dr. Graboff opined that this small rotator cuff tear "would not have on its own spontaneously caused her to develop the signs and symptoms of adhesive capsulitis after the [vaccination]." Pet. Ex. 11 at 4. Additionally, when petitioner was assessed by orthopedist, Dr. Robert Duncan on May 20, 2015, he wrote, "[petitioner] then underwent a glenohumeral joint aspiration which was negative, followed by arthroscopy on Jan. 7, 2014, with only a tiny and likely incidental visualized tear," which is indicative that the small tear would not have been the cause of petitioner's shoulder pain and dysfunction. *See* Pet. Ex. 5 at 286. While petitioner's left shoulder injury improved substantially upon lysis of the lesions in her shoulders and/or repair of the small rotator cuff tear, I am inclined to assign greater significance to the adhesive capsulitis as the source of petitioner's pain and dysfunction rather than the small tear that was "incidentally" visualized during the surgery.

Finally, the acute onset of petitioner's pain and shoulder dysfunction within 2 days after the vaccination is more consistent with an immune-mediated inflammatory response than possible underlying shoulder pathology. Dr. Graboff stated that the vaccination induced an inflammatory response, causing left shoulder adhesive capsulitis. Pet. Ex. 11 at 4. He stated that, "[petitioner] developed a strong inflammatory pain producing response in a reasonable timeframe after vaccination," and that it is not the length of the needle that causes such reaction. Pet. Ex. 12 at 3. Dr. Graboff's opinion is consistent with the medical literature, where the rapid onset of pain and shoulder dysfunction occurred after vaccination both in patients that likely had pre-existing asymptomatic shoulder pathology and those that did not. The explanation that a tiny rotator cuff tear suddenly became symptomatic in the days after the vaccination, having nothing to do with the vaccination, makes much less sense then the explanation of well reported inflammatory pain post intradermal vaccination giving rise to pain protective behavior and adhesive capsulitis.

In this case the cause of the petitioner's pain is also supported by Dr. Gershwin's explanation of the aggressive immune response expected when a vaccine is administered intradermally because of the abundance of macrophages, Langerhan cells and several subsets of dendritic cells present in the intradermal space which is precisely the reason that the intradermal system was introduced. Pet. Ex. 9-E at 1. The studies of adverse responses conducted by the

[17] Siegbert Tempelhof, *Age-related prevalence of rotator cuff tears in asymptomatic shoulders,* 8(4) J. Shoulder Elbow Surg., 296-299 (1999). [Resp. Ex. D Tab 34].

[18] Hiroshi Minagawa, et. al., *Prevalence of Symptomatic and asymptomatic rotator cuff tears in the general population: From mass-screening in one village*, 10 J. of Orthopaedics 8-12 (2013). [Resp. Ex. D Tab 35].

manufacturer also documented shoulder pain in equal or greater numbers as those that occurred with the intramuscular injector.

Therefore, petitioner has established that the October 1, 2013, intradermal flu vaccination was the cause-in-fact of an inflammatory response involving the onset of pain and swelling within 2 days, followed by the development of adhesive capsulitis which resolved following closed manipulation of the shoulder under general anesthesia with reported audible lysis of adhesions during this procedure on January 7, 2014.

b. *Althen* Prong Two

Under *Althen* prong two, petitioner must prove "a logical sequence of cause and effect showing that the vaccination was the reason for [her] injury." *Althen*, 418 F.3d at 1278. This prong is sometimes referred to as the "did it cause" test; i.e. in this particular case, did the vaccine(s) cause the alleged injury. *Broekelschen,* 618 F. 3d at 1345 ("Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case"). Temporal association alone is not evidence of causation. *See Grant v. Sec'y of Health & Human Servs.,* 9556 F.2d 1144, 1148 (Fed. Cir. 1992). This sequence of cause and effect is usually supported by facts derived from petitioner's medical records. *Althen,* 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant*, 956 F.2d at 1148. Treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury. *Paluck v. Sec'y of Health & Human Servs.,* 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu,* 569 F.3d 1375).

Petitioner's experts opined that the flu vaccine caused an inflammatory response, which caused pain around the structures of the shoulder, leading to pain protection behavior and ultimately adhesive capsulitis.

Dr. Schroeder agreed with petitioner's expert Dr. Gershwin that "the vaccine was the proximate cause of the local induration, erythema, edema, and pain at the site of infection…[however] he argued that the fact the vaccine was administered intradermally rules out the proposed causal mechanism of needle entry into the joint and/or bursa of the vaccine into the left shoulder." Resp. Ex. A at 10. As noted above, petitioner's argument is not that the intradermal needle entered the joint and/or bursa of the left shoulder, but instead that the vaccination caused inflammation, which led to ongoing pain and shoulder dysfunction, ultimately leading to adhesive capsulitis. Dr. Graboff opined that the series of events described by petitioner demonstrates a "logical" sequence of events, and the January 7, 2014, left shoulder manipulation confirmed the diagnosis of adhesive capsulitis through the "audible lysis of adhesions." *See* Pet. Ex. 5 at 102; Pet. Ex. 11 at 4; Pet. Mot. at 10. Above, I found that petitioner had provided preponderant evidence of a sound and reliable theory that the intradermal flu vaccination can cause an inflammatory reaction, resulting in pain and shoulder dysfunction. I also conclude that it did in this case.

Prior to receiving the Flu vaccine, petitioner did not experience any injuries or pain in her arms or shoulder. Pet. Aff. ¶ at 5; Pet. Ex. 11 at 3. Petitioner received the intradermal flu

vaccination on October 1, 2013, and immediately felt an electric sensation in her am, and described a pain that she had never experienced during any other vaccination. *Id*. ¶ 4. On October 21, 2013, petitioner presented to the Lahey clinic indicating that she "had a flu vaccine injection through work approximately 2 and half to 3 weeks ago. She reports developing a red hard localized area at the site of injection which gradually resolved." Pet. Ex. 5 at 63. It was noted that "there was no other injury contributing to [her] current symptoms." *Id.* The physical exam revealed petitioner had a "moderate amount of decreased range of motion of the shoulder in all directions, secondary to pain in the anterior posterior rotator cuff." *Id.* at 65. Petitioner was assessed with a "Local reaction to the flu injection," and she was referred to physical therapy. *Id.* The same day petitioner filed an incident report referring to "severe swelling, hard lump, + redness [on] October 8th" Pet. Ex. 4 at 1. Petitioner returned to the Lahey Clinic noting her injury "started as left upper arm/shoulder soreness a few days after she received Flu shot." Pet. Ex. 5 at 66.

Respondent references parts of the medical records in the months between the initial report of pain and the surgery to argue against a diagnosis of adhesive capsulitis, but there are also multiple entries indicating agreement with that diagnosis. Respondent notes that on October 24, 2013, twenty-three days post-vaccination, petitioner indicated to her primary care physician that the lump had resolved, and her PCP did not document any redness or tenderness at that time. Resp. Response at 18; Pet. Ex. 5 at 65. However, respondent conspicuously failed to observe that the medical record from the same day also says, "Left deltoid area with no redness or tenderness. She does have moderate amount of decreased range of motion of the shoulder in all directions secondary to pain in the anterior posterior rotator cuff. No instability. No tenderness of the trapezius area…assessment: *local reaction to flu injection*." Pet. Ex. 5 at 65 (emphasis added).

On October 29, 2013, petitioner visited Dr. McLaughlin for left shoulder pain, and he noted "[Petitioner] presents for evaluation of left shoulder pain that occurred about 3.5-4 weeks ago. She reports -receiving a flu shot to the left arm and 3 days later she began to experience redness, swelling, pain, and stiffness to the left shoulder." Pet. Ex. 6 at 1. Under "impression," Dr. McLaughlin noted that he did not believe her shoulder pain was directly related to the flu vaccine, and he administered a subacromial injection of cortisone in her left shoulder. *Id*. at 2. On November 17, 2013, petitioner underwent an MRI and it noted "a small amount of abnormal fluid within the subdeltoid bursa," which is consistent with inflammation in the bursa. *See* Pet. Ex. 7 at 11. Additionally, the MRI showed a "moderate distal supraspinatus tendinopathy associated with a moderate partial-thickness deep surface tear distally." Pet. Ex. 7 at 12.

On November 19, 2013, petitioner returned to Dr. McLaughlin for an MRI follow up and reported that the cortisone shot from October 29, 2013, did not provide any relief. Pet. Ex. 6 at 4. Dr. McLaughlin noted that petitioner appears to be developing "a picture of Early Frozen shoulder. She has increasing pain and stiffness. No sign of infection of drainage. She also has some rotator cuff tendinopathy but without any obvious tear." *Id*. On December 3, 2013, petitioner returned to Dr. McLaughlin and under "impression," he noted that "she is suffering from what appears to be early and intense frozen shoulder of her left shoulder…I think she may be [have an] inflamed bursa." *Id*. at 5-6.

On December 16, 2013, and petitioner indicated pain "within a few days of the flu vaccination, and on May 20, 2015, petitioner indicated she had "immediate pain." Pet. Ex. 5 at 74-77 and 286-291. Respondent argues that the histories given by petitioner to various treating physicians are not consistent with the medical records regarding what symptoms she experienced and when she experienced them, but the medical records clearly show a progression of pain and shoulder dysfunction starting after the flu vaccine in question. Resp. Response at 18-19.

On January 7, 2014, petitioner underwent a left shoulder arthroscopy with a preoperative diagnosis of left shoulder impingement, and a post-operative diagnosis of left shoulder impingement with rotator cuff tear. Pet. Ex. 5 at 102. The operative note stated that petitioner's left shoulder was manipulated with 20 degrees of abduction and demonstrated "audible lysis of adhesions," followed by the insertion of an arthroscope into the subacromial space and debridement of "hypertrophic synovium and repair of the small tear in the tendon. *Id*. at 103. As concluded above, the shoulder manipulation is a well-accepted treatment for adhesive capsulitis and therefore supports the diagnosis of adhesive capsulitis concluded above particularly when audible lysis of adhesions was noted Petitioner had a follow-up appointment on January 10, 2014, and it was noted that the surgery went well and that she should stay in her shoulder sling as much as possible. *Id*. at 98.

Additionally, two of petitioner's treating physicians, Drs. Smiley and Gantz, associated petitioner's left shoulder pain and dysfunction to the flu shot she received on October 1, 2013. *See* Pet. Ex. 5 at 65 (asserting petitioner had a "significant inflammatory response" to the flu vaccine); Pet. Ex. 5 at 86 (petitioner was diagnosed with a localized reaction to the flu vaccine). Dr. McLaughlin noted on October 29, 2013, that petitioner "reports receiving a flu shot to the left arm and 3 days after she began to experience redness, swelling, pain, and stiffness to the left shoulder." Pet. Ex. 15 at 1.

Respondent's expert, Dr. Schroeder conceded that it was "plausible" that he intradermal flu vaccination was responsible for petitioner's "local induration, erythema, edema, and pain at the sight of injection." Resp. Ex. A at 10. Additionally, Dr. Schroeder also conceded that petitioner's shoulder pain "appeared at about the same time as the local reaction." *Id.* at 11. However, both Drs. Schroeder and Cagle only attribute the resolution of petitioner's shoulder pain to the repair of the tendon tear. *See* Resp. Ex. A at 11; Resp. Ex. F at 5. As discussed above, I found that petitioner had a diagnosis of adhesive capsulitis and that the tear that was found in her shoulder was categorized as "incidental," thus making it more likely that her shoulder pain was the result of adhesive capsulitis and not the tear.

As such, petitioner has demonstrated *Althen* prong two by a preponderance of evidence.

c. *Althen* prong three

Althen prong three requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen* at 1281. That term has equated to the phrase, "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of*

Health & Hum. Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one). *Id.* at 1352.

Respondent argued that petitioner's expert did not offer a "medically-acceptable temporal relationship" between the intradermal flu vaccination and the onset of petitioner's pain and adhesive capsulitis. Resp. Brief at 21. However, petitioner's expert, Dr. Graboff, stated that petitioner's development of adhesive capsulitis occurring "within days of the vaccination," is "well documented in the medical records." Pet. Ex. 11 at 4. He also stated, "The development of localized pain in the days after the injection is typical and can, as it has in this case, be a direct and proximate precursor and the cause of the development of adhesive capsulitis." Pet. Ex. 11 at 4. Respondent's expert, Dr. Schroeder does not dispute the fact that petitioner suffered a "surface reaction at the site of the intradermal injection," and stated that "within a week of the vaccine, [petitioner] developed a localized pain in her left shoulder." *See* Resp. Ex. A at 7.

The Fluzone Intradermal Quadrivalent package insert explained the injection-site adverse reactions, which include pain, pruritis, erythema, swelling, and induration occurred *within* 7 days of vaccination. *See* Resp. Ex. A, Tab 4 at 8. Thus, the medically acceptable temporal relationship between the intradermal flu vaccination and the onset of petitioner's pain is seven days. Additionally, the medical literature filed by both petitioner and respondent support an onset of pain within hours to days of the vaccination. The *Cross* article noted that with intradermal vaccinations, "most patients developed pain and reduced range of motion within a few hours of vaccination, although it can be delayed up to four days." Pet. Ex. 8 Tab 2. [19] The *Atanasoff* article cited by both respondent and petitioner studied 13 cases of shoulder dysfunction following intramuscular vaccination and all the participants "experienced the rapid onset of shoulder pain (range: immediate to four days) following vaccination." Resp. Ex. A, Tab 1. The *Arias* review paper, submitted by respondent, created a systematic review of cases of shoulder injuries in the Spanish Pharmacovigilance System Database ("FEDRA") and found "that the patients had [immediate] pain or pain arising within the first 24 hour post-vaccination in 81.1% of cases, while the remaining 18.9% [had] pain within the 4 first days." Resp. Ex. D Tab 13. [20]

The medical records consistently demonstrate that petitioner associated the onset of her pain and localized injection site reaction within the medically acceptable timeframe established in the literature and referenced by Dr. Graboff. For example, when petitioner returned from her trip from Aruba, she sought medical care on October 21, 2013, petitioner stated that she had a flu vaccine two or three weeks ago and that at the site of injection, she developed a "red, hard, localized area." Pet. Ex. 5 at 63. The record also states, "She now has continued pain in the posterior left shoulder area with decreased range of motion. There was no other injury contributing to current symptoms." *Id.* The same day petitioner filed an incident report referring to "severe swelling, hard lump, + redness [on] October 8th" Pet. Ex. 4 at 1. On October 29, 2018, petitioner visited Dr. McLaughlin for left shoulder pain and he noted "she reports of receiving a

[19] Gail B. Cross, et. al., *Don't aim too high: Avoiding shoulder injury related to vaccine administration,* 45(5) Australian Family Physician 303-306 (2016). [Pet. Ex. 8 Tab 2].

[20] L.H. Martin Arias, et. al., *Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccination,* 35 Vaccine 4870-4876 (2017). [Resp. Ex. D Tab 13].

flu shot to the left arm and 3 days later she began to experience redness, swelling, pain, and stiffness to the left shoulder." Pet. Ex. 6 at 6. On December 16, 2013, it was noted that "within a few days subsequent to the injection she developed a lot of throbbing and soreness in the left shoulder." Pet. Ex. 5 at 74.

Petitioner consistently reported pain and stiffness in her left shoulder as early as two days after the vaccination in question. At her first medical appointment on October 21, 2013, petitioner demonstrated "decreased range of motion in the shoulder in all directions and secondary to pain." Pet. Ex. 5 at 65.

While Dr. Cagle is likely correct that the small tear in the rotator cuff was not caused by the intradermal needle, as noted above, I have concluded that the small tear in the tendon was not the source of petitioner's pain which occurred in close proximity to the vaccination and presented with well reported symptoms of pain, stiffness, redness, and induration. Progression to adhesive capsulitis secondary to pain protective behavior is a much more likely explanation for her ongoing pain and dysfunction leading to the shoulder manipulation and surgery in January 2014.

Consistent with the finding above regarding the onset of petitioner's left shoulder pain and dysfunction, petitioner provided preponderant evidence to satisfy *Althen* prong three.

VI. Conclusion

In accordance with the above I find that petitioner has established by preponderant evidence that she is entitled to compensation, by demonstrating that the flu vaccination administered on October 1, 2013, was the cause-in-fact of her left shoulder pain and ultimate diagnosis of adhesive capsulitis. A separate damages order will be issued.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master